

STATE OF TENNESSEE

OFFICE OF THE
ATTORNEY GENERAL
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Opinion No. 04-115

Over-the-Counter Sale of Non-Corrective, Decorative/Cosmetic Contact Lenses

QUESTIONS

1. Do Tenn. Code Ann. §§ 63-8-102(12) and 63-8-113(a)(6) apply to the retail sale of over-the-counter, non-corrective, decorative/cosmetic contact lenses?
2. Does Tenn. Code Ann. § 63-8-114(4) authorize the Tennessee Board of Optometry to prohibit or regulate the over-the-counter sale of non-corrective, decorative/cosmetic contact lenses?
3. Does Tenn. Code Ann. § 63-1-134(a) authorize the Tennessee Board of Optometry to assess civil penalties against retailers of non-corrective, decorative/cosmetic contact lenses?

OPINIONS

1. No. Since non-corrective, decorative/cosmetic contact lenses do not appear to fall within the Optometry Act's definition of "ophthalmic materials," such sale is neither the "practice of optometry as a profession" as defined in Tenn. Code Ann. § 63-8-102(12), nor does such sale involve testing the vision of any person by any means for the purpose of fitting that person with or prescribing ophthalmic materials, as described in Tenn. Code Ann. § 63-8-113(a)(6).
2. No. Tenn. Code Ann. § 63-8-114(4) prohibits contact lenses from being ordered, sold or dispensed by a retail merchant. However, the Tennessee Board of Optometry may not prohibit or regulate the over-the-counter sale of non-corrective, decorative/cosmetic contact lenses, since such non-corrective, decorative/cosmetic contact lenses are not "ophthalmic materials."
3. No. Since non-corrective, decorative/cosmetic contact lenses are not "ophthalmic materials" under the Act, a retailer of such non-corrective, decorative/cosmetic contact lenses is not "required to be licensed, permitted or authorized" by the Board of Optometry within the meaning of Tenn. Code Ann. § 63-1-134(a). Therefore, that section cannot authorize the Board to assess civil penalties against retailers of non-corrective, decorative/cosmetic contact lenses.

ANALYSIS

1. You have asked whether Tenn. Code Ann. §§ 63-8-102(12) or 63-8-113(a)(6) apply to the retail sale of over-the-counter, non-corrective, decorative/cosmetic lenses. You also have informed this office that the Board of Optometry considers over-the-counter, non-corrective, decorative/cosmetic contact lenses to be ophthalmic materials and medical devices. We understand further that such over-the-counter, non-corrective, decorative/cosmetic contact lenses have a spherical, cylindrical and prismatic power or value of “zero.”¹

The “practice of optometry as a profession” is defined in Tenn. Code Ann. § 63-8-102(12) in pertinent part as meaning:

- (A) The employment of objective or subjective methods (either or both) for the purpose of ascertaining defects of vision or muscular anomalies or other abnormal conditions of the eyes;
- (B) The prescribing of ophthalmic lenses or prisms to remedy or relieve defects of vision or muscular anomalies;
- (C) The orthoptic training, the adjusting, or fitting or adapting of lenses or prisms or eyeglasses or spectacles to remedy or relieve defects of vision or muscular anomalies;
- (D) The supplying, replacement or duplication of an ophthalmic lens or frame;

Tenn. Code Ann. § 63-8-113(a)(6) makes it unlawful for any person not duly licensed in accordance with the Optometry Act, Tenn. Code Ann. §§ 63-8-101, *et seq.*, to “[t]est the vision of any person by any means for the purpose of fitting that person with or prescribing ophthalmic materials.” “Ophthalmic materials,” in turn, is defined by Tenn. Code Ann. § 63-8-102(9):

“Ophthalmic materials” means any lens which has a spherical, cylindrical or prismatic power or value used before or upon the eye and any frame or other appliance used for the purpose of holding or positioning any ophthalmic lenses before the eyes.

Over-the-counter, non-corrective, decorative/cosmetic contact lenses do not appear to us to fall within the above statutory definition of “ophthalmic materials.”² We are not persuaded that a lens with a spherical, cylindrical or prismatic power or value of “zero” in fact has any spherical, cylindrical or prismatic power or value. Further, because the Act does not define the term “medical

¹Such lenses are sometimes referred to as “plano” lenses.

²We note, however, that the ophthalmic practice rules which are contained in the trade regulation rules of the Federal Trade Commission define “ophthalmic goods” as “eyeglasses, or any component of eyeglasses, and contact lenses,” and further define “ophthalmic services” as the “measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.” 16 CFR § 456.1(c) and (d).

device,” we can find no basis for ascertaining that over-the-counter, non-corrective, decorative/cosmetic contact lenses indeed are “medical devices.”³

Moreover, the retail sale of over-the-counter, non-corrective decorative/cosmetic contact lenses does not fall within the meaning of “the practice of optometry as a profession” as defined in Tenn. Code Ann. § 63-8-102(12). Tenn. Code Ann. § 63-8-102(12)(A) concerns “ascertaining defects of vision or muscular anomalies or other abnormal conditions of the eyes,” and the retail sale of non-corrective, decorative/cosmetic contact lenses cannot, by definition, be for such a purpose. Second, Tenn. Code Ann. § 63-8-102(12)(B) concerns the “prescribing of ophthalmic lenses or prisms to remedy or relieve defects of vision or muscular anomalies,” and the retail sale of non-corrective, decorative/cosmetic contact lenses cannot, by definition, involve such prescribing in order to remedy or relieve any defects of vision or muscular anomalies. Third, Tenn. Code Ann. § 63-8-102(12)(C) concerns “the orthoptic training, the adjusting, or fitting or adapting of lenses or prisms or eyeglasses or spectacles to remedy or relieve defects of vision or muscular anomalies,” and the retail sale of non-corrective, decorative/cosmetic contact lenses cannot, by definition, remedy or relieve defects of vision or muscular anomalies. Last, Tenn. Code Ann. § 63-8-102(12)(D) concerns the “supplying, replacement or duplication of an ophthalmic lens or frame,” and since the retail sale of non-corrective, decorative/cosmetic contact lenses does not, in our view, involve “ophthalmic materials” as defined in Tenn. Code Ann. § 63-8-102(9), such sale cannot, by definition, involve supplying an ophthalmic lens.

Therefore, since it is the opinion of this office that such over-the-counter, non-corrective, decorative/cosmetic contact lenses do not fall within the Optometry Act’s definition of “ophthalmic materials,” the retail sale of such items is neither the “practice of optometry as a profession” as defined in Tenn. Code Ann. § 63-8-102(12), nor does it involve testing the vision of any person by any means “for the purpose of fitting that person with or prescribing ophthalmic materials,” as described in Tenn. Code Ann. § 63-8-113(a)(6).

2. Tenn. Code Ann. § 63-8-114 sets forth a number of exemptions to the Act. Included among those exemptions is Tenn. Code Ann. § 63-8-114(4), which provides that nothing in the Act shall be construed

[t]o prevent a retail merchant from selling ready-to-wear spectacles or eyeglasses if such merchant does not assist the customer in fitting or selecting such products or otherwise engage in the practice of

³It is our understanding that legislation may be pending before the Congress to amend the definition of “medical device” in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360j, to include within that definition non-corrective contact lenses and/or all contact lenses. See H.R. 2218 for the 108th Congress (3 versions). Such legislation may address the FDA’s April 4, 2003, announcement that it now considers non-corrective contact lenses to be cosmetics, instead of its previous position that it had jurisdiction over all contact lenses as medical devices. See 68 FR 16520. However, according to the FDA Public Health Web Notification: Non-corrective Decorative Contact Lenses Dispensed Without a Prescription, October 23, 2002, the FDA cautioned consumers against using decorative contact lenses that have not been prescribed or fitted by a qualified eye care professional.

optometry. However, contact lenses may not be ordered, sold or dispensed by a retail merchant.

Notwithstanding the import of the last sentence of this exemption provision, we do not believe that it may logically be construed as an independent source of authority to prohibit the over-the-counter sale of non-corrective, decorative/cosmetic contact lenses. This is because the sentence appears in an exemption to a statutory scheme that, for the reasons stated above, does not even regulate the sale of such devices.

3. Tenn. Code Ann. § 63-1-134(a) provides:

With respect to any person required to be licensed, permitted or authorized by any board, commission or agency attached to the division of health related boards, each respective board, commission or agency may assess a civil penalty against such person in an amount not to exceed one thousand dollars (\$1,000) for each separate violation of a statute, rule or order pertaining to such board, commission or agency. Each day of violation constitutes a separate violation.

Since non-corrective, decorative/cosmetic contact lenses are not “ophthalmic materials” under the Optometry Act, a retailer of such non-corrective, decorative/cosmetic contact lenses is not “required to be licensed, permitted or authorized” by the Board of Optometry within the meaning of Tenn. Code Ann. § 63-1-134(a). Therefore, that section cannot authorize the Board to assess civil penalties against retailers of non-corrective, decorative/cosmetic contact lenses.

However, we understand that the Board’s concern about the retail sale of over-the-counter, non-corrective, decorative/cosmetic contact lenses stems from its belief that such devices have caused and may continue to cause serious eye injuries. By way of analogy to the Dispensing Opticians Act, Tenn. Code Ann. § 63-14-101, *et seq.*, which concerns the preparation, adaptation and dispensing of lenses, the Supreme Court wrote in *Tennessee Board of Dispensing Opticians v. Eyear Corporation*, 218 Tenn. 60, 72, 400 S.W.2d 734, 740(1966):

The eyes of the average individual are probably one of the most delicate organs of the individual. It certainly was the purpose of the Legislature in passing this Act to require trained and licensed individuals to do these things so as to protect in every way the eyes of the individual. The Legislature clearly felt, and it was their intention, in enacting this Act that such an Act had a direct and real connection with the health and welfare of the general public, and the purpose of the Act was to protect such health and welfare.

In that regard, and viewing the purpose of the Optometry Act as concomitant with that of the

Dispensing Opticians Act, the Board of Optometry might wish to consider approaching the Legislature in order to seek to amend the Optometry Act in order to include the retail sale of over-the-counter, non-corrective, decorative/cosmetic contact lenses within the Optometry Act's definition of "ophthalmic materials." Several states, for example, specifically regulate "plano contact lenses," "zero-powered contact lenses," and/or "contact lenses in any of their forms" through their respective licensing boards. Among the more instructive state statutes is an Oklahoma statute regulating the sale of optical goods and devices. 59 Okl. St. Ann. § 942(C) provides:

1. It is hereby prohibited and declared contrary to the public health and public policy of this state to dispense, supply, fit, adjust, adapt, or in any manner apply contact lenses to the eyes of a person whether or not those contact lenses are designed to aid or correct human vision or are plano or cosmetic contact lenses, without a prescription issued by a person licensed pursuant to Chapter 11, Chapter 13 or Chapter 14 of this title.
2. The Board of Examiners in Optometry may secure an injunction, without bond, in the district courts to prevent the dispensing, supplying, fitting, adjusting, or adapting of any contact lens without a prescription.
3. As used in this section, "plano" means a contact lens with no prescription power.

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